# S. 3144

To amend part B of title XVIII of the Social Security Act to delay and reform the Medicare competitive acquisition program for purchase of durable medical equipment, prosthetics, orthotics, and supplies.

### IN THE SENATE OF THE UNITED STATES

June 17, 2008

Mr. Baucus (for himself, Mr. Grassley, Ms. Stabenow, Mr. Voinovich, Mr. Salazar, Mr. Roberts, Mr. Brown, Mr. Smith, Mr. Casey, Ms. Collins, Mr. Levin, Mrs. Dole, Mr. Lieberman, Mr. Isakson, Mr. Wyden, Mr. Burr, Mr. Dodd, Ms. Snowe, Mr. Sanders, Mr. Hatch, Ms. Cantwell, Mr. Cardin, Mr. Schumer, Mrs. Clinton, Ms. Mikulski, and Mrs. Lincoln) introduced the following bill; which was read twice and referred to the Committee on Finance

## A BILL

To amend part B of title XVIII of the Social Security Act to delay and reform the Medicare competitive acquisition program for purchase of durable medical equipment, prosthetics, orthotics, and supplies.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Medicare DMEPOS
- 5 Competitive Acquisition Reform Act of 2008".

1	SEC. 2. DELAY IN AND REFORM OF MEDICARE DMEPOS
2	COMPETITIVE ACQUISITION PROGRAM.
3	(a) Temporary Delay and Reform.—
4	(1) In General.—Section 1847(a)(1) of the
5	Social Security Act (42 U.S.C. 1395w-3(a)(1)) is
6	amended—
7	(A) in paragraph (1)—
8	(i) in subparagraph (B)(i), in the
9	matter before subclause (I), by inserting
10	"consistent with subparagraph (D)" after
11	"in a manner";
12	(ii) in subparagraph (B)(i)(II), by
13	striking "80" and "in 2009" and inserting
14	"an additional 70" and "in 2011", respec-
15	tively;
16	(iii) in subparagraph (B)(i)(III), by
17	striking "after 2009" and inserting "after
18	2011 (or, in the case of national mail order
19	for items and services, after 2010)"; and
20	(iv) by adding at the end the following
21	new subparagraphs:
22	"(D) Changes in competitive acquisi-
23	TION PROGRAMS.—
24	"(i) Round 1 of competitive ac-
25	QUISITION PROGRAM.—Notwithstanding
26	subparagraph (B)(i)(I) and in imple-

1	menting the first round of the competitive
2	acquisition programs under this section—
3	"(I) the contracts awarded under
4	this section before the date of the en-
5	actment of this subparagraph are ter-
6	minated, no payment shall be made
7	under this title on or after the date of
8	the enactment of this subparagraph
9	based on such a contract, and, to the
10	extent that any damages may be ap-
11	plicable as a result of the termination
12	of such contracts, such damages shall
13	be payable from the Federal Supple-
14	mentary Medical Insurance Trust
15	Fund under section 1841;
16	"(II) the Secretary shall conduct
17	the competition for such round in a
18	manner so that it occurs in 2009 with
19	respect to the same items and services
20	and the same areas, except as pro-
21	vided in subclauses (III) and (IV);
22	"(III) the Secretary shall exclude
23	Puerto Rico so that such round of
24	competition covers 9, instead of 10, of

1	the largest metropolitan statistical
2	areas; and
3	"(IV) there shall be excluded
4	negative pressure wound therapy
5	items and services.
6	Nothing in subclause (I) shall be construed
7	to provide an independent cause of action
8	or right to administrative or judicial review
9	with regard to the termination provided
10	under such subclause.
11	"(ii) Round 2 of competitive ac-
12	QUISITION PROGRAM.—In implementing
13	the second round of the competitive acqui-
14	sition programs under this section de-
15	scribed in subparagraph (B)(i)(II)—
16	"(I) the metropolitan statistical
17	areas to be included shall be those
18	metropolitan statistical areas selected
19	by the Secretary for such round as of
20	June 1, 2008; and
21	"(II) the Secretary may sub-
22	divide metropolitan statistical areas
23	with populations (based upon the
24	most recent data from the Census Bu-
25	reau) of at least 8,000,000 into sepa-

1	rate areas for competitive acquisition
2	purposes.
3	"(iii) Exclusion of certain areas
4	IN SUBSEQUENT ROUNDS OF COMPETITIVE
5	ACQUISITION PROGRAMS.—In imple-
6	menting subsequent rounds of the competi-
7	tive acquisition programs under this sec-
8	tion, including under subparagraph
9	(B)(i)(III), for competitions occurring be-
10	fore 2015, the Secretary shall exempt from
11	the competitive acquisition program (other
12	than national mail order) the following:
13	"(I) Rural areas.
14	"(II) Metropolitan statistical
15	areas not selected under round 1 or
16	round 2 with a population of less than
17	250,000.
18	"(III) Areas with a low popu-
19	lation density within a metropolitan
20	statistical area that is otherwise se-
21	lected, as determined for purposes of
22	paragraph (3)(A).
23	"(E) Verification by oig.—The Inspec-
24	tor General of the Department of Health and
25	Human Services shall, through post-award

audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

# "(F) SUPPLIER FEEDBACK ON MISSING FINANCIAL DOCUMENTATION.—

"(i) IN GENERAL.—In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

"(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such

1	programs) after the covered document
2	review date, for notice to the bidder of
3	all such documents that are missing
4	as of the covered document review
5	date; and
6	"(II) may not reject the bid on
7	the basis that any covered document
8	is missing or has not been submitted
9	on a timely basis, if all such missing
10	documents identified in the notice pro-
11	vided to the bidder under subclause
12	(I) are submitted to the Secretary not
13	later than 10 business days after the
14	date of such notice.
15	"(ii) Covered document review
16	DATE.—The covered document review date
17	specified in this clause with respect to a
18	competitive acquisition program is the
19	later of—
20	"(I) the date that is 30 days be-
21	fore the final date specified by the
22	Secretary for submission of bids
23	under such program; or
24	"(II) the date that is 30 days
25	after the first date specified by the

1	Secretary for submission of bids
2	under such program.
3	"(iii) Limitations of process.—
4	The process provided under this subpara-
5	graph—
6	"(I) applies only to the timely
7	submission of covered documents;
8	"(II) does not apply to any deter-
9	mination as to the accuracy or com-
10	pleteness of covered documents sub-
11	mitted or whether such documents
12	meet applicable requirements;
13	"(III) shall not prevent the Sec-
14	retary from rejecting a bid based on
15	any basis not described in clause
16	(i)(II); and
17	"(IV) shall not be construed as
18	permitting a bidder to change bidding
19	amounts or to make other changes in
20	a bid submission.
21	"(iv) Covered document de-
22	FINED.—In this subparagraph, the term
23	'covered document' means a financial, tax,
24	or other document required to be sub-
25	mitted by a bidder as part of an original

1	bid submission under a competitive acqui-
2	sition program in order to meet required
3	financial standards. Such term does not in-
4	clude other documents, such as the bid
5	itself or accreditation documentation.";
6	and
7	(B) in paragraph (2)(A), by inserting be-
8	fore the period at the end the following: "and
9	excluding certain complex rehabilitative power
10	wheelchairs recognized by the Secretary as clas-
11	sified within group 3 or higher (and related ac-
12	cessories when furnished in connection with
13	such wheelchairs)".
14	(2) Budget neutral offset.—
15	(A) In General.—Section 1834(a)(14) of
16	such Act (42 U.S.C. 1395m(a)(14)) is amend-
17	ed—
18	(i) by striking "and" at the end of
19	subparagraphs (H) and (I);
20	(ii) by redesignating subparagraph (J)
21	as subparagraph (M); and
22	(iii) by inserting after subparagraph
23	(I) the following new subparagraphs:
24	"(J) for 2009—

1	"(i) in the case of items and services
2	furnished in any geographic area, if such
3	items or services were selected for competi-
4	tive acquisition in any area under the com-
5	petitive acquisition program under section
6	1847(a)(1)(B)(i)(I) before July 1, 2008,
7	including diabetic supplies but only if fur-
8	nished through mail order, - 9.5 percent;
9	or
10	"(ii) in the case of other items and
11	services, the percentage increase in the
12	consumer price index for all urban con-
13	sumers (U.S. urban average) for the 12-
14	month period ending with June 2008;
15	"(K) for 2010, 2011, 2012, and 2013, the
16	percentage increase in the consumer price index
17	for all urban consumers (U.S. urban average)
18	for the 12-month period ending with June of
19	the previous year;
20	"(L) for 2014—
21	"(i) in the case of items and services
22	described in subparagraph (J)(i) for which
23	a payment adjustment has not been made
24	under subsection (a)(1)(F)(ii) in any pre-
25	vious year, the percentage increase in the

1	consumer price index for all urban con-
2	sumers (U.S. urban average) for the 12-
3	month period ending with June 2013, plus
4	2.0 percentage points; or
5	"(ii) in the case of other items and
6	services, the percentage increase in the
7	consumer price index for all urban con-
8	sumers (U.S. urban average) for the 12-
9	month period ending with June 2013;
10	and".
11	(B) Conforming treatment for cer-
12	TAIN ITEMS AND SERVICES.—The second sen-
13	tence of section $1842(s)(1)$ of such Act $(42)$
14	U.S.C. 1395u(s)(1)) is amended by striking
15	"except that" and all that follows and inserting
16	the following: "except that for items and serv-
17	ices described in paragraph (2)(D)—
18	"(A) for 2009 section $1834(a)(14)(J)(i)$ shall
19	apply under this paragraph instead of the percent-
20	age increase otherwise applicable; and
21	"(B) for 2014, if subparagraph (A) applied to
22	the items and services and there has not been a pay-
23	ment adjustment under subsection $(h)(1)(H)$ for the
24	items and services for any previous year, the per-
25	centage increase computed under section

1	1834(a)(14)(L)(i) shall apply instead of the percent-
2	age increase otherwise applicable.".
3	(3) Conforming Delay.—Subsections
4	(a)(1)(F) and $(h)(1)(H)$ of section 1834 of the So-
5	cial Security Act (42 U.S.C. 1395m) are each
6	amended by striking "January 1, 2009" and insert-
7	ing "January 1, 2011".
8	(4) Considerations in application.—Sec-
9	tion 1834 of such Act (42 U.S.C. 1395m) is amend-
10	$\operatorname{ed}$ —
11	(A) in subsection (a)(1)—
12	(i) in subparagraph (F), by inserting
13	"subject to subparagraph (G)," before
14	"that are included"; and
15	(ii) by adding at the end the following
16	new subparagraph:
17	"(G) Use of information on competi-
18	TIVE BID RATES.—The Secretary shall specify
19	by regulation the methodology to be used in ap-
20	plying the provisions of subparagraph (F)(ii)
21	and subsection (h)(1)(H)(ii). In promulgating
22	such regulation, the Secretary shall consider the
23	costs of items and services in areas in which
24	such provisions would be applied compared to

1	the payment rates for such items and services
2	in competitive acquisition areas."; and
3	(B) in subsection (h)(1)(H), by inserting
4	"subject to subsection (a)(1)(G)," before "that
5	are included".
6	(b) Quality Standards.—
7	(1) Application of accreditation require-
8	MENT.—
9	(A) In general.—Section 1834(a)(20) of
10	the Social Security Act (42 U.S.C.
11	1395m(a)(20)) is amended—
12	(i) in subparagraph (E), by inserting
13	"including subparagraph (F)," after
14	"under this paragraph,"; and
15	(ii) by adding at the end the following
16	new subparagraph:
17	"(F) APPLICATION OF ACCREDITATION RE-
18	QUIREMENT.—In implementing quality stand-
19	ards under this paragraph—
20	"(i) subject to clause (ii), the Sec-
21	retary shall require suppliers furnishing
22	items and services described in subpara-
23	graph (D) on or after October 1, 2009, di-
24	rectly or as a subcontractor for another en-
25	tity, to have submitted to the Secretary

1	evidence of accreditation by an accredita-
2	tion organization designated under sub-
3	paragraph (B) as meeting applicable qual-
4	ity standards; and
5	"(ii) in applying such standards and
6	the accreditation requirement of clause (i)
7	with respect to eligible professionals (as
8	defined in section 1848(k)(3)(B)), and in-
9	cluding such other persons, such as
10	orthotists and prosthetists, as specified by
11	the Secretary, furnishing such items and
12	services—
13	"(I) such standards and accredi-
14	tation requirement shall not apply to
15	such professionals and persons unless
16	the Secretary determines that the
17	standards being applied are designed
18	specifically to be applied to such pro-
19	fessionals and persons; and
20	"(II) the Secretary may exempt
21	such professionals and persons from
22	such standards and requirement if the
23	Secretary determines that licensing,
24	accreditation, or other mandatory
25	quality requirements apply to such

1	professionals and persons with respect
2	to the furnishing of such items and
3	services.".
4	(B) Construction.—Section
5	1834(a)(20)(F)(ii) of the Social Security Act,
6	as added by subparagraph (A), shall not be con-
7	strued as preventing the Secretary of Health
8	and Human Services from implementing the
9	first round of competition under section 1847
10	of such Act on a timely basis.
11	(2) Disclosure of subcontractors under
12	COMPETITIVE ACQUISITION PROGRAM.—Section
13	1847(b)(3) of such Act $(42$ U.S.C. $1395w-3(b)(3))$
14	is amended by adding at the end the following new
15	subparagraph:
16	"(C) DISCLOSURE OF SUBCONTRAC-
17	TORS.—
18	"(i) Initial disclosure.—Not later
19	than 10 days after the date a supplier en-
20	ters into a contract with the Secretary
21	under this section, such supplier shall dis-
22	close to the Secretary, in a form and man-
23	ner specified by the Secretary, the infor-
24	mation on—

1	"(I) each subcontracting relation-
2	ship that such supplier has in fur-
3	nishing items and services under the
4	contract; and
5	"(II) whether each such subcon-
6	tractor meets the requirement of sec-
7	tion $1834(a)(20)(F)(i)$ , if applicable
8	to such subcontractor.
9	"(ii) Subsequent disclosure.—Not
10	later than 10 days after such a supplier
11	subsequently enters into a subcontracting
12	relationship described in clause (i)(II),
13	such supplier shall disclose to the Sec-
14	retary, in such form and manner, the in-
15	formation described in subclauses (I) and
16	(II) of clause (i).".
17	(3) Competitive acquisition ombudsman.—
18	Such section is further amended by adding at the
19	end the following new subsection:
20	"(f) Competitive Acquisition Ombudsman.—The
21	Secretary shall provide for a competitive acquisition om-
22	budsman within the Centers for Medicare & Medicaid
23	Services in order to respond to complaints and inquiries
24	made by suppliers and individuals relating to the applica-
25	tion of the competitive acquisition program under this sec-

1	tion. The ombudsman may be within the office of the
2	Medicare Beneficiary Ombudsman appointed under sec-
3	tion 1808(c). The ombudsman shall submit to Congress
4	an annual report on the activities under this subsection,
5	which report shall be coordinated with the report provided
6	under section $1808(c)(2)(C)$ .".
7	(c) Change in Reports and Deadlines.—
8	(1) GAO REPORT.—Section 302(b)(3) of the
9	Medicare Prescription Drug, Improvement, and
10	Modernization Act of 2003 (Public Law 108–173) is
11	amended—
12	(A) in subparagraph (A)—
13	(i) by inserting "and as amended by
14	section 2 of the Medicare DMEPOS Com-
15	petitive Acquisition Reform Act of 2008"
16	after "as amended by paragraph (1)"; and
17	(ii) by inserting before the period at
18	the end the following: "and the topics spec-
19	ified in subparagraph (C)";
20	(B) in subparagraph (B), by striking "Not
21	later than January 1, 2009," and inserting
22	"Not later than 1 year after the first date that
23	payments are made under section 1847 of the
24	Social Security Act,"; and

1	(C) by adding at the end the following new
2	subparagraph:
3	"(C) Topics.—The topics specified in this
4	subparagraph, for the study under subpara-
5	graph (A) concerning the competitive acquisi-
6	tion program, are the following:
7	"(i) Beneficiary access to items and
8	services under the program, including the
9	impact on such access of awarding con-
10	tracts to bidders that—
11	"(I) did not have a physical pres-
12	ence in an area where they received a
13	contract; or
14	"(II) had no previous experience
15	providing the product category they
16	were contracted to provide.
17	"(ii) Beneficiary satisfaction with the
18	program and cost savings to beneficiaries
19	under the program.
20	"(iii) Costs to suppliers of partici-
21	pating in the program and recommenda-
22	tions about ways to reduce those costs
23	without compromising quality standards or
24	savings to the Medicare program.

1	"(iv) Impact of the program on small
2	business suppliers.
3	"(v) Analysis of the impact on utiliza-
4	tion of different items and services paid
5	within the same Healthcare Common Pro-
6	cedure Coding System (HCPCS) code.
7	"(vi) Costs to the Centers for Medi-
8	care & Medicaid Services, including pay-
9	ments made to contractors, for admin-
10	istering the program compared with ad-
11	ministration of a fee schedule, in compari-
12	son with the relative savings of the pro-
13	gram.
14	"(vii) Impact on access, Medicare
15	spending, and beneficiary spending of any
16	difference in treatment for diabetic testing
17	supplies depending on how such supplies
18	are furnished.
19	"(viii) Such other topics as the Comp-
20	troller General determines to be appro-
21	priate.".
22	(2) Delay in other deadlines.—
23	(A) Program advisory and oversight
24	COMMITTEE.—Section 1847(c)(5) of the Social
25	Security Act (42 U.S.C. 1395w-3(c)(5)) is

- 1 amended by striking "December 31, 2009" and 2 inserting "December 31, 2011".
  - (B) SECRETARIAL REPORT.—Section 1847(d) of such Act (42 U.S.C. 1395w–3(d)) is amended by striking "July 1, 2009" and inserting "July 1, 2011".
    - (C) IG REPORT.—Section 302(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) is amended by striking "July 1, 2009" and inserting "July 1, 2011".
    - (3) EVALUATION OF CERTAIN CODE.—The Secretary of Health and Human Services shall evaluate the existing Healthcare Common Procedure Coding System (HCPCS) code for negative pressure wound therapy to ensure accurate reporting and billing for items and services under such code. In carrying out such evaluation, the Secretary shall use the existing process for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such process.

#### 22 (d) Other Provisions.—

(1) EXEMPTION FROM COMPETITIVE ACQUISITION FOR CERTAIN OFF-THE-SHELF ORTHOTICS.—

Section 1847(a) of the Social Security Act (42)

1	U.S.C. 1395w-3(a)) is amended by adding at the
2	end the following new paragraph:
3	"(7) Exemption from competitive acquisi-
4	TION.—The programs under this section shall not
5	apply to the following:
6	"(A) CERTAIN OFF-THE-SHELF
7	ORTHOTICS.—Items and services described in
8	paragraph (2)(C) if furnished—
9	"(i) by a physician or other practi-
10	tioner (as defined by the Secretary) to the
11	physician's or practitioner's own patients
12	as part of the physician's or practitioner's
13	professional service; or
14	"(ii) by a hospital to the hospital's
15	own patients during an admission or on
16	the date of discharge.
17	"(B) CERTAIN DURABLE MEDICAL EQUIP-
18	MENT.—Those items and services described in
19	paragraph (2)(A)—
20	"(i) that are furnished by a hospital
21	to the hospital's own patients during an
22	admission or on the date of discharge; and
23	"(ii) to which such programs would
24	not apply, as specified by the Secretary, if
25	furnished by a physician to the physician's

1	own patients as part of the physician's
2	professional service.".
3	(2) Correction in face-to-face examina-
4	TION REQUIREMENT.—Section 1834(a)(1)(E)(ii) of
5	such Act (42 U.S.C. 1395m(a)(1)(E)(ii)) is amended
6	by striking " $1861(r)(1)$ " and inserting " $1861(r)$ ".
7	(3) Special rule in case of national mail-
8	ORDER COMPETITION FOR DIABETIC TESTING
9	STRIPS.—Section 1847(b) of such Act (42 U.S.C.
10	1395w-3(b)) is amended—
11	(A) by redesignating paragraph (10) as
12	paragraph (11); and
13	(B) by inserting after paragraph (9) the
14	following new paragraph:
15	"(10) Special rule in case of competition
16	FOR DIABETIC TESTING STRIPS.—
17	"(A) IN GENERAL.—With respect to the
18	competitive acquisition program for diabetic
19	testing strips conducted after the first round of
20	the competitive acquisition programs, if an enti-
21	ty does not demonstrate to the Secretary that
22	its bid covers types of diabetic testing strip
23	products that, in the aggregate and taking into
24	account volume for the different products, cover
25	50 percent (or such higher percentage as the

Secretary may specify) of all such types of products, the Secretary shall reject such bid.

The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

"(B) Study of types of testing strip products.—Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquisition program described in subparagraph (A).".

(4) Other conforming amendments.—Section 1847(b)(11) of such Act, as redesignated by paragraph (3), is amended—

1	(A) in subparagraph (C), by inserting "and
2	the identification of areas under subsection
3	(a)(1)(D)(iii)" after " $(a)(1)(A)$ ";
4	(B) in subparagraph (D), by inserting
5	"and implementation of subsection $(a)(1)(D)$ "
6	after "(a)(1)(B)";
7	(C) in subparagraph (E), by striking "or"
8	at the end;
9	(D) in subparagraph (F), by striking the
10	period at the end and inserting "; or"; and
11	(E) by adding at the end the following new
12	subparagraph:
13	"(G) the implementation of the special rule
14	described in paragraph (10).".
15	(5) Funding for implementation.—In addi-
16	tion to funds otherwise available, for purposes of im-
17	plementing the provisions of, and amendments made
18	by, this section, other than the amendment made by
19	subsection $(e)(1)$ and other than section
20	1847(a)(1)(E) of the Social Security Act, the Sec-
21	retary of Health and Human Services shall provide
22	for the transfer from the Federal Supplementary
23	Medical Insurance Trust Fund established under
24	section 1841 of the Social Security Act (42 U.S.C.
25	1395t) to the Centers for Medicare & Medicaid Serv-

- 1 ices Program Management Account of \$20,000,000
- 2 for fiscal year 2008, and \$25,000,000 for each of
- 3 fiscal years 2009 through 2012. Amounts trans-
- 4 ferred under this paragraph for a fiscal year shall be
- 5 available until expended.
- 6 (e) Effective Date.—The amendments made by
- 7 this section shall take effect as of June 30, 2008.

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